Collaboration between stakeholders underpinned by dynamic information exchange is the prerequisite of a systems-based market. If other industry sectors such as consumer goods, finance and telecommunications serve as a model for systems-thinking, we will expect novel linkages between health care stakeholders to become more prevalent as population health goals unifies incentives. While many acknowledge the need to move toward a more integrated "systems thinking" approach – one that maps influence patterns, amplifies interdependencies, and drives collective outcomes, they struggle with actual implementation. A recent survey of close to 300 Biopharma executives, EU and US Payers, and US providers reveals insight into their needs, their disparate perceptions, and their levels of confidence in the ability to shift to a systems-thinking collaborative culture. Approximately 25% of respondents stated they were not aligned with other stakeholders, though agree they need better alignment and foresee closer collaboration in the future. More than 70% of stakeholders believe data transparency and information-sharing is critically important to a successful and interoperable health care system, yet very few from each group were willing to demonstrate such transparency. Most health care industry stakeholders are ill prepared for the necessary trust-building activities required by this anticipated transition. A viable and sustainable information network provides the structure, aligned incentives and competitive collaboration the bricks and mortar, and trust the cornerstone. Until they can build that and foster a culture of transparency, they won't achieve the cost and innovation benefits inherent in these cross-industry partnerships. Further detail will be given on insights and challenges gleaned from interviewing large and small stakeholders as well as practical strategies, such as experimentation with data integration projects, to guide the transformation to a systems-thinking industry.

DISEASE-SPECIFIC STUDIES

GASTROINTESTINAL DISORDERS – Clinical Outcomes Studies

PGI1

COMPARATIVE EFFICACY AND SAFETY OF GOLIMUMAB, INFLIXIMAB AND ADALIMUMAB FOR THE TREATMENT OF MODERATE TO SEVERE ULCERATIVE COLITIS: A BAYESIAN INDIRECT TREATMENT COMPARISON META-ANALYSIS

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OBJECTIVES: To compare the relative efficacy and safety of golimumab, infliximab and adalimumab for the treatment of moderate-to-severe ulcerative colitis using indirect treatment comparison (ITC) meta-analysis. **METHODS:** A systematic literature search identified five randomized controlled trials. Outcomes of interest included clinical remission, clinical response, mucosal healing, sustained remission/response, serious adverse events (SAEs), and discontinuation due to adverse events (DAEs). Data was synthesized using Bayesian indirect treatment comparison (ITC) meta-analysis. The analysis incorporated advanced intention-to-treat with baseline priors to account for the alternative design of the golimumab trial. **RESULTS:** After the induction phase, each treatment had significantly greater efficacy than placebo all endpoints, with the exception of adalimumab for mucosal healing. No statistical differences were observed between golimumab and infliximab. Adalimumab had significantly lower efficacy measures compared to infliximab for clinical remission (odds ratio [OR] 0.42, 95% credible interval [CrI] 0.17-0.97), clinical response (OR 0.45, 95% CrI 0.23-0.89), and mucosal healing (OR 0.46, 95% CrI 0.25-0.84) after the induction period. During the maintenance phase, each biologic agent exhibited significantly greater efficacy compared to placebo for clinical remission, clinical response, and mucosal healing. Golimumab 100mg was significantly better than adalimumab for clinical response (OR 1.80, 95% CrI 1.01-3.21) and mucosal healing at 54 weeks (OR 1.88, 95% CrI 1.01-3.49). No statistical differences were observed between adalimumab and infliximab. Both golimumab 100mg and infliximab were significantly better than adalimumab in terms of sustained clinical response (OR 2.40, 95% CrI 1.17-4.86 and OR 1.93, 95% CrI 1.04-4.06), respectively. For SAEs, there were no statistical differences between any of the biologics and placebo. Although all biologics were generally safe, golimumab 100mg had statistically significantly higher DAEs when compared to adalimumab (OR 2.09, 95% CrI 1.07-4.17). **CONCLUSIONS:** In the context of ITC meta-analysis, both golimumab and infliximab appear to demonstrate superior efficacy-safety profiles compared with adalimumab.

PGI2

SURGICAL SITE INFECTION AFTER CHOLECYSTECTOMY: RATES AND OPERATIVE RISK FACTORS

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OBJECTIVES: Over 500,000 cholecystectomies are performed in the U.S. annually. The incidence of surgical site infection (SSI) is higher after open compared to laparoscopic cholecystectomy, but other procedural risk factors for SSI have not been well established. We investigated operative risk factors for SSI following cholecystectomy in a large cohort of privately insured patients. **METHODS:** We performed a retrospective cohort study of persons aged 18–64 years with ICD-9-CM procedure or CPT-4 codes for cholecystectomy from 1/1/2004–12/31/2010 using commercial insurer claims data. Complex procedures and patients (e.g., cancer, end-stage renal disease) were excluded. SSIs occurring within 90 days after cholecystectomy were identified by ICD-9-CM diagnosis codes. Procedures in which SSI or septicemia was coded ≤30 days before surgery were also excluded. Multivariable logistic regression was used to determine independent risk factors for SSI, controlling for age. **RESULTS:** A total of 113,138 cholecystectomy procedures were identified; 76% were performed in females and the median age was 43 years (range 18–64). A total of 833 (0.74%) SSIs occurred; the SSI incidence was higher for open procedures (90 [4.85%] open versus 743 [0.67%] laparoscopic; p<0.001). Independent risk factors for SSI included acute cholecystitis (odds ratio [OR], 1.53; 95% confidence interval [CI], 1.32–1.77), choledocholithiasis (OR, 1.44; 95% CI, 1.10–1.88), open approach (OR, 5.51; 95% CI, 4.00–7.61) laparoscopic converted to open approach (OR, 5.48; 95% CI, 3.99–7.54), and concurrent bile duct repair (OR, 4.76; 95% CI, 1.93–11.70). Females had significantly decreased risk of SSI (OR, 0.75; 95% CI, 0.65–0.88). **CONCLUSIONS:** Acute cholecystitis, choledocholithiasis, and concurrent bile duct repair were associated with increased risk of SSI after cholecystectomy, controlling for open surgery, age, and gender. Our findings suggest that stratification of SSI rates by these operative factors is important when comparing rates between facilities.

PGI3

WORKING TITLE: CONTRAINDICATIONS FOR HCV THERAPY IN UNITED STATES PATIENTS WITH UNTREATED CHRONIC HEPATITIS C (CHC)

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OBJECTIVES: Describe the prevalence of contraindications to chronic hepatitis C (CHC) treatment among CHC patients not receiving CHC treatment (direct-acting antiviral [DAA] protease inhibitors, peg-interferon alpha, or ribavirin). **METHODS:** Adult patients with ≥2 CHC diagnoses (ICD-9-CM codes 070.44, 070.54, 070.70, 070.71) and no DAA fills at any time in their claims history were selected from a de-identified US-based claims database (2010-2012); the first CHC diagnosis after 5/13/2011 was defined as the index date. Patients with CHC treatment 6-months before or 12 months after the index date were excluded. All patients were required to have continuous eligibility and no claims for hepatitis B during the 6-months before (baseline) and 12-months after their index dates. Contraindications (based on a World Health Organization hepatitis C guide) during the baseline period were identified based on ICD-9 codes and described for the overall cohort as well as stratified by age (18-39; 40-49; 50-59; 60-69; 70-79; 80+). **RESULTS:** There were 12,726 untreated patients identified, of which 7,644 (60.1%) had ≥1 baseline contraindication to peg-interferon or ribavirin. Untreated patients were 56 years old on average and more often male (61%). Approximately 86.8% of the untreated cohort had no claim for any CHC treatment any time in their claims history. The most common contraindications included arterial hypertension (32.1%), hepatic decompensation (22.3%), major system impairment (19.2%), and psychiatric depression (11.0%). Age-stratified results showed increasing prevalence of contraindications with age; rates of contraindications increased from 44.2% among patients 18-39 to 76.65% among patients 80 years old and older. **CONCLUSIONS:** A high proportion of untreated CHC patients had diagnoses for contraindicated conditions, and the prevalence of these contraindications increased with age.

PGI4

INFLUENCE OF LORNOXICAM INTRAVENOUS INJECTIONS ON MORTALITY IN PATIENTS WITH ACUTE PANCREATITIS: A PROPENSITY SCORE-MATCHED ANALYSIS

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OBJECTIVES: Acute pancreatitis (AP) is associated with significant morbidity and mortality, representing a severe economic burden for health care system. Numerous attempts were made to find medications able to inhibit secretion of pancreatic enzymes and/or inflammatory cytokines in patients with AP to prevent further destruction of pancreas. There exist some evidences demonstrating that a cyclooxygenase inhibitor lornoxicam may inhibit secretion of inflammatory cytokines. The objective of the study was to investigate if lornoxicam administration might be clinically and economically beneficial in patients with AP. **METHODS:** Patients with AP were admitted in a Moscow hospital in 2010-2011. All of them were treated according to existing Russian standards of AP treatment. Part of patients were administered with lornoxicam iv bid during the first 5 days of hospitalization (16-32 mg a day). The information on the patients was collected using electronic health records (EHR) and then analyzed. Due to differences in baseline characteristics of the groups of patients treated and non-treated with lornoxicam, propensity scores matching technique was used. Logistic regression model was built to calculate propensity to be treated with lornoxicam for each patient. Then mortality rates were compared for the matched cohorts treated and non-treated with lornoxicam. Finally, the cost of one prevented death was calculated. **RESULTS:** Totally 264 patients were identified in EHR, lornoxicame was administered to 74 patients. Propensity scores adjusted mortality rate was 6.0% for lornoxicam group and 20.0% for control group (p=0.037). Thus, administration of lornoxicam might prevent mortality in 14% patients with AP. The cost of the 5-day course of lornoxicam was 2,602 RUB (78 USD). Therefore, the cost of one prevented death due to AP was 18,586 RUB (556 USD). **CONCLUSIONS:** It was demonstrated that intravenous injections of lornoxicam in patients with AP was not only potentially life-saving, but also cost effective, given the low cost of one prevented death.

PGI5

PREVALENCE AND RISK FACTORS OF HEPATITIS B AND C AMONG THE BARBARS AND THEIR REGULAR CLIENTS IN HYDERABAD, PAKISTAN

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OBJECTIVES: To determine the Prevalence and risk factors of Hepatitis B & C among the Barbers and their regular shaving clients in the Hyderabad Barber Shops of Pakistan. **METHODS:** A cross sectional study was conducted to determine the sero-prevalence of Hepatitis-B virus (HBV) and Hepatitis-C virus (HCV) among barbers and their clients in Hyderabad Sindh Pakistan and to assess their knowledge, attitude and practices regarding these two viruses and their mode of transmission. Sampling was done by using a-2-stage sampling techniques. A close

ended and open ended multi-country questionnaire was designed to collect data from 715 participants (186 Barbers and 529 Clients). Blood samples were withdrawn after obtaining an informed consent and were tested for HBV and HCV markers by Chromatography, enzyme-lined immunosorbent assay (ELISA) and polymerase chain reaction (PCR). **RESULTS:** The mean age was 28.47±9.7 years in both groups of Barbers (n-186) and Clients (n=529). Among both groups, the sero-prevalence of HBV and HCV was 5.7% and 14.4%, respectively. Clients knew about hepatitis B and C viruses while barbers were not quite aware. The knowledge about the route of transmission was poor among barbers and good among clients. Half of the respondents in both groups knew about hepatitis B vaccination and only 15% were vaccinated. Sixty percent of the barbers claimed disinfecting the instruments between clients and (88.9%) claimed using of new blades. During actual observation of practices, only 28% disinfected instruments between clients and 62% used new blades for each client. **CONCLUSIONS:** There is some awareness among barbers and clients about hepatitis B and C viruses but poor knowledge about the mode of transmission. This warrants conducting health education campaigns to increase awareness about these two blood borne viruses and the risk factors associated with their transmission particularly at barbers' shop and to implement interventions to prevent spreading Hepatitis.

GASTROINTESTINAL DISORDERS – Cost Studies

PGI6

AN ASSESSMENT OF THE ECONOMIC IMPACT OF MECHANICAL VERSUS HAND-SUTURED FIXATION OF INTRA-PERITONEAL ONLAY MESH (IPOM) IN OPEN VENTRAL HERNIA REPAIR

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OBJECTIVES: Reduction in operative time has been shown to offer significant clinical benefits in many procedures including hernia repair surgeries. Ethicon Securestrap™ Open, a new mechanical absorbable strap fixation device, takes significantly shorter time compared to hand-sutured fixation of IPOM mesh in open ventral hernia surgery. This analysis assesses the potential economic value of reduction in operative time with mechanical fixation compared to suture fixation. **METHODS:** An economic model was developed to evaluate the budget impact to hospitals of adopting Ethicon Securestrap™ Open repair of ventral hernia. A reduction in mean fixation time comparing suture to mechanical fixation was included based on a preclinical study that demonstrated about 89% reduction. Related benefits in terms of risk of surgical site infections, owing to shorter operative duration were included based on the literature. Costs of the mechanical fixation device and suture supplies, OR time, anesthesia time, and potentially avoided surgical site infections were considered in the economic model. **RESULTS:** Based on the model inputs, an overall potential saving of $259,604 (43%) was estimated for 100 fixations if they were done using Ethicon Securestrap™ Open versus sutures. Although the use of Ethicon Securestrap™ Open added $50,000 in supplies costs, this was completely offset by potential savings in OR time costs ($186,570), potential reduction in avoided surgical site infection or seroma costs due to shorter operating room time ($104,210), and in anesthesia costs ($14,324). Use of Ethicon Securestrap™ Open was also estimated to be potentially freeing up a total of about 58 hours in OR time per 100 conversions. **CONCLUSIONS:** This analysis represents the first economic evaluation of Ethicon Securestrap™ Open use in open ventral hernia surgery. Adoption of Ethicon Securestrap™ Open fixation device would likely result in significant savings for hospitals, driven by shorter procedure time and its related clinical benefits.

PGI7

COST ANALYSIS OF A FIBRIN SEALANT PATCH FOR PARENCHYMAL BLEEDING DURING ELECTIVE HEPATIC SURGERY: A GERMANY HOSPITAL PERSPECTIVE

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OBJECTIVES: Hemostasis after liver resection may be difficult to achieve and there is thus an increased focus on reducing blood loss and resource use with hemostatic products. This study estimated the cost impact of a novel fibrin sealant patch (i.e., EVARREST) vs. standard of care (SoC) for bleeding control in hepatic resection. **METHODS:** An economic analysis quantified 30-day cost impact of EVARREST vs. SoC from a German hospital perspective. This analysis used data from a randomized trial, which included aggregated resource use reported within 30 days. Resources included initial treatment and re-treatment, operating time, hospitalization, transfusions, and ventilator. SoC was composed of manual compression with a small percentage using hemostats. The primary analysis included resources clinically related to the significant hemostasis benefit of EVARREST vs. SoC (i.e., initial treatment and re-treatment with hemostasis methods, operating time, transfusions, and blood units). A secondary analysis included all resources evaluated in the primary analysis with the addition of hospital stay, proportion of patients using ventilator, and mean ventilator hours. A projected global price for EVARREST was used based on average USD to Euro exchange rate over the last 10 years. Published data on German costs were applied to resource use. Sensitivity analyses were conducted on several variables including EVARREST costs (€472 to €735) for available sizes. **RESULTS:** The primary analysis predicted that EVARREST acquisition cost is offset with cost impact reduced to €82 per patient vs. SoC (sensitivity range: -€86 to €225). Secondary analyses predicted further resource reduction with EVARREST leading to cost-savings (i.e., -€458 per patient). Operating time and hospital stay were important analysis drivers. **CONCLUSIONS:** This analysis suggests that EVARREST may result in cost savings, in addition to meeting an important unmet need for controlling bleeding in hepatic surgery. Further study in more patients may be required to confirm findings.

PGI8

MEDICARE HEPATITIS C PATIENTS – ARE PATIENTS UNDER 65 DIFFERENT?

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OBJECTIVES: Previous studies have shown that the majority of Medicare patients with HCV are under age 65. This study examines how patient characteristics and cost differ between Medicare patient age groups. **METHODS:** An analysis of HCV patients was conducted using the 2010-2011 Centers for Medicare and Medicaid Services Parts A and B fee-for-service claims. Patients with an HCV ICD-9 code and 6 months of follow-up were included. Patient characteristics, resource utilization and 6-month costs were compared between patients age<65 and age≥65. The impact of age on medical costs adjusting for demographics, reason for entitlement(OREC), Medicaid status, and overall health status (measured by CCI) was assessed using generalized linear models fit with a gamma distribution and log link function. **RESULTS:** 16,417 HCV patients with complete data were identified. Patients under 65 (n=11,286) were more likely to have an OREC of disability (89%), while patients 65+ OREC was primarily due to old age and survivors insurance (80%). ESRD accounted for 8.8% of patients age<65 and 1.7% aged 65+. Medicaid dual-eligibility was twice as common among younger patients (38.0% vs. 66.8%, p<0.01). Younger patients had a higher prevalence of alcoholism (35.6% vs. 30.6%, p<0.01) and drug abuse (43.3% vs. 12.2%, p<0.01), comorbidities that are also risk factors for HCV. Yet overall health, as measured by CCI, was higher for younger patients (1.82 vs. 2.51, p<0.01). Younger patients had more hospitalizations (0.48 vs 0.33, p<0.01) and emergency department visits (2.04 vs. 1.77, p<0.01). 6-month medical costs for patients age<65 were $1,285 higher than those 65+ (p=0.01). After adjusting for OREC, HCV-related comorbidities, CCI, demographics and Medicaid status, age was no longer associated with cost. **CONCLUSIONS:** Medicare HCV patients under 65 are more expensive to treat. However, this appears to be due to higher rates of disability, ESRD and comorbidities, rather than age itself.

PGI9

COST OF ILLNESS (COI) ASSOCIATED WITH GASTROINTESTINAL AND LIVER DISEASE: A STUDY CONDUCTED AT AN INDIAN TERITARY CARE HOSPITAL

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OBJECTIVES: To study cost of illness (COI) by calculating direct and indirect cost in the patients with gastrointestinal and liver disease from societal perspective. **METHODS:** Study was conducted in general medicine ward of government tertiary care hospital, north India by including inpatients diagnosed with gastrointestinal and liver disorders. In terms of time perspective prevalence approach was used to study COI. Direct cost was estimated using admission fee, cost of bed, diet charge, cost of medications and diagnostic tests/surgical procedures. Indirect cost was estimated using loss of wages, travelling cost, food cost, and cost of bed for attendant/s of patient due to hospital stay. Estimated costs were converted to purchasing power parity dolor (PPP$) for cross country comparison. To estimate the productivity loss, human capital approach was used with assumption that income reflects productivity. **RESULTS:** A total 202 patients (83% males) were included in the study. Most prevalent disorder includes alcoholic liver disease (32.5%) and most common class of drug prescribed was proton pump inhibitor (94%). Majority of the patients (53%) with these diseases has hospital stay of 1 to 7 days. The total direct costs and indirect cost of disease for study patients were PPP$ 23518 and PPP$ 30187 respectively. Direct and indirect cost of disease for each patient was PPP$ 231 and PPP$ 277 respectively. The cost of medication (17.8%) and loss of wages (43.9%) contributes major component of direct and indirect cost respectively. Total cost for males (PPP$ 276.0±145) is significantly higher (P <0.05) than the total cost for females (PPP$ 232.6±146.6). Mean direct and indirect costs incurred by female patients were significant less than that of male patients. **CONCLUSIONS:** Cost of medication and loss of wages of patients contributes major component of COI. Increasing the number of day of hospital stay leads to higher cost of burden.

PGI10

ESTIMATION OF HEPATITIS C COSTS IN TURKEY VIA EXPERT OPINION: DELPHI PANEL

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OBJECTIVES: The aim of the study is to estimate the cost of Hepatitis C in Turkey through reaching consensus on the current clinical practice, resource use and the course of treatment. **METHODS:** This study uses the Delphi method to reach experts' consensus on the clinical practices currently being used in Turkey. Delphi method has been widely used in medical areas where empirical data is scarce. The survey developed for this study includes questions to understand the clinical resource use in order to calculate the associated costs. According to the literature, the panelists' answers are unlikely to change after the second iteration. Similar to theory, a two-iteration panel was needed to reach a consensus in practice. The consensus is then used to calculate the cost of chronic hepatitis C, compensated cirrhosis, decompensated cirrhosis, hepatocarcinoma and liver transplant health states from the payer's perspective. **RESULTS:** The Delphi panel included gastroenterologists, infectious diseases specialists and a gastroenterologist with transplantation experience. According to panel consensus, among all of the patients that an expert follows, the rate of patients who need hepatitis C treatment (regardless of diagnosis) is 1% for gastroenterologists and 20% for infectious diseases specialists.